Checklist

Organizational and Structural Activities for Reprocessing Medical Devices

This checklist is intended to support the organization and structure of activities which are necessary to reprocess medical devices. It also can be used as a self-check before an inspection by relevant authorities. This checklist does not claim to be complete.

**Legally Required Instructions / Education / Training of Staff * / ** **	**Yes**	**No**	**Not applicable**
Health and safety, e.g., changing chemicals, chemical exposure monitoring (if applicable)	○	○	○
Hygiene and infection prevention, e.g., correct dosage of cleaning/disinfecting solutions	○	○	○
Competency training and assessment for all employees recommended at initial hire (minimum once a year, documented) for (new) endoscope models/equipment/products	○	○	○
Injuries and accidents	○	○	○
Maternity protection	○	○	○
Fire protection	○	○	○
Hazardous and biological substances	○	○	○
Data protection	○	○	○
Lift and carry	○	○	○
Ladders and step aids	○	○	○
Screen work	○	○	○
First aid	○	○	○
Outbreak management: reporting obligations and procedures in the event of incidents involving staff and/or medical devices	○	○	○
Failure concept in case of breakdown of washer disinfector or sterilizer, closing of reprocessing department, etc.	○	○	○
Regular performance of microbiological tests for flexible endoscopes (DIN EN ISO 15883 and national guidelines)	○	○	○

*Content may vary between different countries.
**Please also consider external cleaning staff.

Infection Prevention

	Yes	No	Not applicable
Training and education (minimum once a year for all employees, documented)	○	○	○
Hygiene Plan Providing All Best Practices for Hygienic Behavior, e.g.: · Clothing (e.g., different clothing for different working areas). · Laundry and suitable laundry collecting containers. · Cleaning/disinfection of all floors in different areas with and without infection risk. · Waste and suitable waste containers for different types of waste including waste containers for pointed and sharp objects. · Reprocessing dispensers (for hand disinfection, soap and lotion). · No jewelry, no watches, no nail polish, short fingernails, no artificial fingernails. · Correct performance of hand disinfection. · Description of reprocessing room(s): Separation into a “clean” and “unclean/dirty” area for proper hygienic workflow, organizationally or by separated rooms. · Description of standard operating procedure (SOP) of reprocessing medical devices and necessary reprocessing utensils (manually and/or automated). · Sufficient PPE (personal protective equipment), such as gloves, goggles, mouth and nose protection, protective gown/apron. · Company doctor: regular appointments and health checks (e.g., vaccination, staff training for hand hygiene). · etc.	○	○	○
Cleaning and disinfection plan: what is done when, by whom, with what, and do all disinfectants have the required spectrum of activity?	○	○	○
Are there enough and correctly equipped hand-washing/disinfection places available?	○	○	○
Is there the correct PPE (personal protective equipment) for the different activities (patient procedures, reprocessing of instruments, etc.)?	○	○	○

Dealing with Medical Devices

	Yes	No	Not applicable
Are all active medical devices listed in an inventory? e.g., washer disinfector, ultrasonic cleaners, endoscopes, sterilizers, etc.	○	○	○
Are instructions for use (IFU) (including reprocessing) available for all medical devices?	○	○	○
Are maintenance, repairs, validation and routine tests (if applicable) carried out in accordance with the IFU / manufacturer’s specifications?	○	○	○
Has a risk assessment and classification of the medical devices (Spaulding classification) to be reprocessed been carried out?	○	○	○
Have the responsibilities for all reprocessing steps been defined and documented (standard operating procedure (SOP)/organization chart)?	○	○	○
Are there written SOPs and documentation for all processing steps (manually and automated)?	○	○	○

If the Reprocessing Is Carried Out Externally:

	Yes	No	Not applicable
Is it ensured that the external reprocessing facility is professionally capable of reprocessing medical devices correctly and in accordance with all applicable guidelines?	○	○	○
Are the transport times fixed and documented within the legal frame?	○	○	○
Is there a contract with the reprocessing facility for external reprocessing?	○	○	○
Are the interfaces regarding pretreatment at the point of use and/or manual cleaning that might be necessary after surgical/endoscopic procedure defined?	○	○	○
Definition and observance of time intervals between end of procedure and starting reprocessing as described in guidelines (e.g., think of organizing pickup and delivery service)	○	○	○

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